



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0107; FRL-9399-4]

Spirotetramat; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spirotetramat in or on corn, sweet, kernel plus cob with husks removed and persimmon and revises established tolerances in or on feijoa, papaya, and Spanish lime, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0107, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: RDFNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0107 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0107, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for spirotetramat including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spirotetramat follows.

In the **Federal Register** of July 17, 2013 (78 FR 42736) (FRL-9391-6), the EPA proposed, on its own initiative under FFDCA section 408(e), 21 U.S.C. 346a(e), to establish a tolerance for residues of the insecticide spirotetramat in or on corn, sweet, kernel plus cob with husks removed at 1.5 parts per million (ppm) and persimmon at 2.5 ppm. Additionally, EPA proposed to revise 40 CFR 180.641 by amending established tolerances in or on feijoa from 0.30 ppm to 2.5 ppm, papaya from 2.5 ppm to 0.40 ppm, and Spanish lime from 0.60 ppm to 13 ppm. The proposed rule referenced a recently published spirotetramat final rule printed in the **Federal Register** of May 15, 2013 (78 FR 28507) (FRL-9382-8); in the risk assessments associated with that final rule, the EPA also considered these proposed uses. Since that time, the toxicity profile of spirotetramat has not changed, and the risk assessments that supported the establishment of those spirotetramat tolerances published in the May 15, 2013 **Federal Register** final rule remain valid. For a detailed discussion of the aggregate risk assessments and determination of safety that support these new and revised uses, please refer to the May 15, 2013 **Federal Register** final rule and its supporting documents, available at <http://www.regulations.gov>.

Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to spirotetramat residues. EPA relies upon the findings made in the May 15, 2013 **Federal Register** final rule and the underlying risk assessments in order to establish the new and revised tolerances as detailed in the July 17, 2013 **Federal Register** proposed rule.

III. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, a high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS), is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established a MRL for spirotetramat in or on papaya at 0.4 milligram/kilogram (mg/kg). This MRL is the same as the tolerance established for spirotetramat in or on papaya at 0.40 ppm in the United States. There are no Codex MRLs established for the other commodities associated with this final rule.

C. Response to Comments

The EPA received one comment to the proposed rule which stated that no tolerances should be allowed for spirotetramat. The commenter expressed a general opposition to the use of “toxic chemicals” on food and faulted EPA for not conducting toxicity testing that combined spirotetramat with the “thousands” of other approved pesticides. The Agency understands the commenter’s concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food. However, the existing legal framework provided by FFDCA section 408 states that tolerances may be set when the pesticide meets the safety standard imposed by that statute. The Agency is required by FFDCA section 408 to estimate the risk of the potential exposure to these residues. EPA has concluded that there is a reasonable certainty that no harm will result from aggregate human exposure to spirotetramat residues from these uses. As far as the toxicity testing relied upon by EPA, testing requirements for pesticide tolerances have been specified by rulemaking after allowing for notice and comment by the public and peer review by appropriate scientific bodies. See 40 CFR part 158. Toxicity testing of a pesticide in combination with all other approved pesticides is neither required by the testing regulations nor practical.

IV. Conclusion

Therefore, tolerances are established for residues of spirotetramat, (cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate) and its metabolites, cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-

D-glucopyranoside-, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, calculated as the stoichiometric equivalent of spirotetramat, in or on corn, sweet, kernel plus cob with husks removed at 1.5 ppm; and persimmon at 2.5 ppm. Additionally, the regulation amends established tolerances in or on feijoa from 0.30 ppm to 2.5 ppm, papaya from 2.5 ppm to 0.40 ppm, and Spanish lime from 0.60 ppm to 13 ppm.

V. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption

provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 25, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.641, in the table in paragraph (a)(1):

a. Add alphabetically “corn, sweet, kernel plus cob with husks removed” and “persimmon”; and

b. Revise the entries for “feijoa,” “papaya,” and “Spanish lime”.

The additions and revisions read as follows:

§ 180.641 Spirotetramat; tolerances for residues.

(a) * * *

(1) * * *

| Commodity | Parts per million |
|---|-------------------|
| * * * | * * |
| Corn, sweet, kernel plus cob with husks removed | 1.5 |
| * * * | * * |
| Feijoa | 2.5 |
| * * * | * * |
| Papaya | 0.40 |
| * * * | * * |
| Persimmon | 2.5 |
| * * * | * * |
| Spanish lime | 13 |
| * * * | * * |

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